

"Each 1 cc. contains: Thiamin HCl . . . 20 mg. Riboflavin . . . 1 mg.," since the article contained no thiamine or riboflavin.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the intravenous dosage recommended, suggested, and prescribed in the labeling.

**DISPOSITION:** October 11, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1752. Misbranding of Re-Sude-Olds. U. S. v. 49 Dozen Packages of Re-Sude-Olds. Default decree of condemnation and destruction. (F. D. C. No. 16375. Sample No. 17509-H.)**

**LABEL FILED:** June 25, 1945, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about May 18, 1945, from Los Angeles, Calif., by the American Medical Products, Inc.

**PRODUCT:** 49 dozen packages of *Re-Sude-Olds* at Chicago, Ill. Examination showed that the product contained approximately one-half grain each of thyroid and potassium iodide per capsule.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented and suggested that the article was an appropriate and effective treatment for obesity due to hypothyroidism caused by deficient action of the thyroid gland, the pituitary gland, or the ovarian gland. The article was neither an appropriate nor an effective treatment for obesity, whether or not due to hypothyroidism resulting from such causes.

Further misbranding, Section 502 (j), the article would be dangerous to health, because of its content of thyroid, when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: (Carton) "When administering these capsules the dose for an average person, depending upon his requirements, may often be one capsule daily for six days, then one capsule twice a day for six days, then one capsule three times a day as long as treatment is continued"; (bottle label) "It is suggested that the dose for an average person, depending upon his requirements, may often be one capsule daily for six days, then one capsule twice a day for six days, then one capsule three times a day as long as treatment is continued."

**DISPOSITION:** October 30, 1945: No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

### **DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

**1753. Misbranding of Fentone Compound. U. S. v. Will T. Warren, Jr. (Fentone Medicine Co.). Plea of nolo contendere. Fine, \$2,000; jail sentence of 60 days. (F. D. C. No. 14250 Sample Nos. 41524-F, 61323-F.)**

**INFORMATION FILED:** June 13, 1945, Western District of Tennessee, against Will T. Warren, Jr., trading as the Fentone Medicine Co., Paris, Tenn.

**ALLEGED SHIPMENT:** Between the approximate dates of August 2 to September 22, 1943, from the State of Tennessee into the State of Mississippi.

**LABEL, IN PART:** "Blythe and Fentress Fentone Compound."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statement, "Liver & Bile Stimulant," and certain statements in the accompanying circulars were false and misleading since they represented and suggested that the article would be efficacious as a liver and bile stimulant and kidney flusher; that it would be efficacious in the correction of intestinal stasis, and would prevent the spreading of poisons throughout the system and the contamination of the blood stream, liver, and kidneys as a result of intestinal stasis; that it would cause the heart, stomach, intestines, bladder, lungs, liver, and kidneys to work perfectly and regularly; that it would be efficacious in removing deep-seated impurities from the stomach, acid deposits in the kidneys, and pockets of impurity; that it would remove excess acid and bacteria; that it would be efficacious to relieve back pains and bring about a feeling of new life and happiness; that it would be efficacious in the cure, mitigation, treatment, and prevention of high blood pressure, rheumatism, arthritis symptoms, nervousness, loss of sleep, backache, belching and bloating, spitting of burning, hot, half-digested food, pains in the back, stiffness in the joints, and tired, run-

down, dizzy feelings; that it would be efficacious in the treatment of kidneys and liver which are overtaxed with poison-filled blood, and would reduce pressure on the different digestive organs and enable them to return to normal, natural function; that it would be efficacious to correct poisoned, loaded, overworked, strained, and irritated organs, and would cause the appetite to pick up and the user to feel active and full of energy, hope, and ambition; that it would be efficacious in the treatment of heartburn, heart palpitation, and swollen stomach caused by poison pockets in the intestinal tract; that it would be efficacious to correct upset stomachs, clogged liver, constipation, packed colon, too much acid in kidneys, headache, and dizziness; that it would cause the liver bile to wake up and contribute aid in flushing the kidneys and stomach of harmful deposits; that it would quiet hyperacidity of the stomach and kidneys and remove toxic poisons and impurities from the alimentary canal; that it would be efficacious in the treatment of nausea, vomiting, pain, and discomfort, a burning feeling at the lower end of the breastbone, heartburn, and the coughing up of sour, acid liquid in the mouth; that it would be efficacious in the treatment of bilious headache and a languid, tired, worn-out feeling; that it would cause the kidneys to become normal and healthy; that it would keep the blood pure and free from bacteria and prevent deposits of acid and accumulated waste in the kidney tubes; that it would be efficacious in the treatment of irritation, sleeplessness, pain, worry, a dull, achy feeling across the small of the back, frequent getting up at night, loss of vigor, swollen joints, symptoms of rheumatism, symptoms of neuritis, swollen ankles, and leg pains; and that it would be efficacious in the treatment of coated tongue and bad breath. The article would not be efficacious for the purposes stated.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage or methods or duration of administration as are necessary for the protection of users, since the directions, "Adults—One to two Tablespoonfuls two times a day in a glass of water before eating, as needed. Increase dose if necessary. \* \* \* Should this medicine disagree with you in any way, then reduce amount taken, or discontinue entirely until such disagreement has worn off and does not return upon resuming taking of this medicine," provided for continual use, whereas the article was a laxative and should not have been used continuously.

**DISPOSITION:** September 20, 1945. The defendant having entered a plea of nolo contendere, the court imposed a fine of \$1,000 on each count, a total fine of \$2,000, and a sentence of 60 days in jail.

**1754. Misbranding of Milford Mineral Water Crystals. U. S. v. 23 Dozen Packages of Mineral Water Crystals, and a number of display cards. Default decree of condemnation and destruction. (F. D. C. No. 15356. Sample Nos. 28325-H, 28326-H.)**

**LABEL FILED:** April 16, 1945, Western District of Washington.

**ALLEGED SHIPMENT:** On or about February 6, 1945, by the Pecan Shellers Cooperative, from Houston, Tex.

**PRODUCT:** 11½ dozen 8-ounce packages and 11½ dozen sample packages of *mineral water crystals*, and a number of accompanying display cards entitled "Why You Need Mineral Water," at Seattle, Wash.

Examination showed that the product consisted of sodium sulfate with traces of other ingredients. It was essentially a laxative.

**LABEL, IN PART:** "Milford Blue Ribbon Mineral Water Crystals."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the labels of the sample packages were false and misleading since they represented and suggested that the article would be effective in the treatment of rheumatism, arthritis, heart trouble, kidney trouble, high and low blood pressure, overweight, underweight, paralysis, stomach and colon troubles, asthma, hay fever, eczema, and sores caused by excess acidity; and that it would supply mineral elements to the body. The article would not be effective in the treatment of the disease conditions mentioned, and it would not supply mineral elements to the body. Further misbranding, Section 502 (a), the statement "Gives You Benefits You Never Dreamed Of," borne on the display card, was false and misleading since it created the impression that the article was more than a laxative; and the statement of composition, "Analysis shows Sodium Chloride, Sodium Sulphate, Silica, Potassium Chloride, Calcium Bicarbonate, Calcium Sulphate, Ferri Oxide, Alumina Oxide, Magnesium Sulphate," borne on the packages containing both sizes of the product, was mis-